Davis Wright Tremaine LLP

Health Law Advisory Bulletin

HHS Offers Cautious Protections for E-Prescribing and EHR Subsidies

By Thomas E. Jeffry, Jr.
[October 2005]

The HHS Inspector General and the Administrator of CMS separately published in Tuesday's Federal Register much-anticipated proposed rules that would allow hospitals, group practices, prescription drug plan (PDP) sponsors and Medicare Advantage (MA) organizations to provide physicians with technology for electronic prescribing as well as for interoperable electronic health records without running afoul of either the federal Anti-kickback statute or the physician self referral (Stark) law.

The protections for e-prescribing technology are required by the Medicare Modernization Act of 2003 (MMA), which created the Medicare prescription drug benefit that goes into effect next year. The MMA requires final standards for Medicare e-prescribing by 2008. HHS has taken an incremental approach to the e-prescribing standards: it published proposed standards for prescriptions and related eligibility transactions in February; now comes the proposed anti-kickback safe harbor and a similar exception to the Stark law, and other standards, such as formulary, medication history, drug interaction and general medical history will be adopted as they are developed and accredited.

Relying on its general authority to develop new anti-kickback statute safe harbors, the OIG also solicited comments on a broader proposed rule describing the elements (but not the language) of a safe harbor for hospitals and others to provide electronic health record (EHR) technology and training to physicians. CMS in its proposed rule addressing EHR included language for two additional exceptions to the Stark physician self-referral prohibition. The essential elements of both the CMS and OIG proposals are substantially the same and both proposed rules are open for public comment for 60 days.

Eighteen months ago, the president called for adoption of interoperable electronic health records on a national scale within 10 years and established the Office of the National Coordinator for Health Information Technology to spearhead the effort. Concerns over regulatory restrictions on providing technology and other benefits to physicians— described in our bulletin of a year ago http://www.dwt.com/practc/hit/bulletins/10-04_Stark.htm—have hampered the development of EHR networks, and there have been widespread calls for flexibility. The proposed regulations are intended to address these concerns and would remove a potential obstacle to providing qualifying technology to physicians in order to encourage adoption of electronic prescribing and use of EHR. The narrow scope of the proposed exceptions, however, virtually guarantees that Stark and Anti-kickback restrictions will continue to impair the development of EHR.

One of the challenges that OIG and CMS face is the lack of standards for EHRs, either for content or for interoperability. There has certainly been progress: HL7 has developed a draft functional model of an EHR system and the Commission on Systemic Interoperability, which was established by the MMA, is expected to report to Congress this month. But it is difficult to write a safe harbor for something when no one can say quite what it is. CMS addressed this in its proposed rule by creating two separate Stark exceptions related to EHR. The first exception applies to EHR items and services that are not certified and the second exception applies to certified items and services. The second exception will automatically take effect when the technology is certified in accordance with criteria adopted by HHS.

The OIG is considering a similar phased regulation: Initially, the safe harbor would protect donations of any EHR system that includes e-prescribing capability, and perhaps also computerized order entry (but not other types of technology, such as billing and general practice management). Once interoperability

and product certification standards are established, a replacement safe harbor would protect donations of systems meeting the standards, and possibly including additional capabilities beyond the core functions of EHR, e-prescribing and CPOE.

E-Prescribing

Following its statutory mandate, the OIG proposes to create a safe harbor for "Donors" to give "Recipients" the technology necessary to transact e-prescribing. Permissible Donors are hospitals (to members of their medical staff), PDPs or MA plans (to prescribers and pharmacies), and medical groups (to their members).

In contrast, CMS proposes a Stark exception focused on physicians and their staff as the 'Recipients' to take into account the more limited application of the physician self-referral law. Otherwise, the criteria for the Stark exception and the anti-kickback safe harbor are similar.

The technology that may be given is broad, and includes hardware, software, training and Internet access. However, the other limits on what may be given do much to take away that breadth. The OIG expressed its intent to set a cap on the retail value of donated items and asked for public input on how such a cap is determined. The items donated—

- Must be necessary for e-prescribing;
- Must be used "only" for e-prescribing; and,
- Must be something that the recipient does not already have.

In commentary, the OIG draws some interesting distinctions. Software suites are disfavored, because valuable general office management, billing, scheduling, or other software might be bundled with the electronic prescribing features. Hardware, operating systems and Internet access, however, must only be used "substantially" for the purpose of e-prescribing. (The OIG solicits input on how "substantial use" can be defined.)

The specific elements of the safe harbor and Stark exception include:

- The items and services must be used to access an electronic prescription drug program that meets Medicare's standards.
- The donor may not restrict the use or compatibility of the items or services with other systems.
- The donor may not restrict the recipient's ability to use the items or services for any patient.
- The recipient may not make the receipt of items or services a condition of doing business with the donor.
- Neither the eligibility nor amount of the items or services may be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.
- The arrangement must be set forth in a written agreement that—
    - Is signed by the parties;
    - Specifies the items or services being provided and the value of those items and services;
    - Covers all of the electronic prescribing items and services to be furnished by the donor (or affiliated parties) to the recipient; and,

- Contains a certification by the recipient that the items and services are not "technically or functionally equivalent" to items and services the recipient already has.

- The donor must not have actual knowledge of or otherwise act in reckless disregard or ignorance of the fact that the recipient already had technically or functionally equivalent items to those donated.

What constitutes the functional equivalent of some other technology is likely to generate some interesting questions. According to the comments by the OIG and CMS, a hand-held device may be donated even if the physician has a desk top computer, but a new computer may not be given because an upgrade is desirable. Also unclear, is how far a donor must go to ascertain whether the recipient has functionally equivalent items.

Electronic Medical Records

With respect to EHR, CMS and the OIG took a different approach. CMS actually proposed two new Stark exceptions that are mutually exclusive based upon whether the technology and services donated are certified under anticipated HHS guidelines. The OIG described a safe harbor that contains similar elements to what CMS proposed, but decided to solicit comments before formalizing any language into a rule.

The OIG recognizes that physicians are not alone in their reluctance to change software programs. Once a person achieves some level of comfort with a software program, inertia sets in. If the software has a proprietary format that is incompatible with other competing programs, then it might "tie" the physician to that software and the vendor that makes it available. The solution: require the software to be "interoperable," which means it must work with the systems of competitors.

Because there are no standards defining an interoperable electronic medical record, this requirement delays indefinitely the necessity to define other components of the safe harbor. It also will be interesting to see the enthusiasm that software designers bring to the project.

Although not a complete list, the OIG solicits comments on the following:

- Whether the e-prescribing software should allow physicians to order supplies or laboratory tests.

- Whether and how to address Recipients who give away their technology in order to get the free replacement.

- The software functions that should be included in the definition of "electronic health records," include:

    - types of software that should be protected;

    - retail and nonretail cost of such software;

    - manner in which such software is currently marketed;

    - methods for defining the scope of protected software; and

    - safeguards that might be imposed to ensure that provision of the software cannot be used to camouflage unlawful payments for referrals or to tie Recipients to Donors,

- What to do about rural providers who do not have the same access to technology.

- Whether to require certifications by Recipients that they do not already have electronic health records.

- Whether to impose a cap on donations, including—
    - an aggregate dollar cap;
    - a cap that would be set at a percentage of the value of the technology to the recipient (thus requiring Recipients to share a portion of the costs and reducing windfall benefits to Recipients); or
    - a cap set at the lower of a fixed dollar amount or a percentage of the value of the technology to the recipient.
- Whether and, if so, how to take into account recipient access to any software that is publicly available either free or at a reduced price.
- Whether other categories of Donors or Recipients should be included and why.

The CMS proposed Stark exception proposes similar elements to those offered in the e-prescribing exception. Items and services must be "necessary" and "used solely" to receive, transmit, and maintain EHR. However, the donated items and services permitted under the exception are limited to software and direct training services and do not include hardware or equipment. Permissible Donors are also limited to hospitals (to members of its medical staff), PDPs or MA plans, and medical groups (to its members). Both the pre- and post-certification exceptions require a written agreement and specify similar limitations related to compatibility, restrictions on use, and eligibility determinations.

Unique to these EHR exceptions are the additional requirements that:

- The EHR technology must contain electronic prescribing capability that complies with Medicare Part D standards; and,
- The arrangement does not violate the anti-kickback statute.

The pre-certification rule prohibits the donation of items and services that include billing, scheduling, or general office management and services as well as office staffing services. In contrast, the post-certification rule prohibits office staffing services and those items and services used solely to conduct business of the physician that is personal or unrelated to his or her medical practice. Of course, under the post-certification rule, all donated technology must be certified in accordance with HHS criteria.

Although the eligibility of the physician to receive donated items and services along with the amount and nature of such services cannot take account of the volume or value of referrals or other business generated between the donor and the physician, the post-certification rule expressly permits the following types of economic criteria in making such determinations:

- Total number of prescriptions written by the recipient.
- Size of the recipient's medical practice (e.g. total patients, total patient encounters, or RVUs)
- Total number of hours the recipient practices medicine.
- Recipient's overall use of automated technology in the practice unrelated to specific referrals made to the donor.
- If the donor is a hospital, whether the physician is on the medical staff.
- Other criteria developed in a 'reasonable and verifiable manner' not directly related to referrals and business generation between the parties.

Commentary

There is a strong political push to encourage adoption of certain health information technologies. The proposed rules take the first steps to remove certain obstacles by shifting the costs of adoption from physicians and small providers to hospitals, PCP and MA plans, and other payors. At the same time, these rules seek to maintain the traditional tight controls over arrangements that may lead to referrals.

Congress and the Administration have clearly staked out positions on both sides of a yawning chasm and instructed CMS and the OIG to bridge the gap. On one side of the canyon, lawmakers have clearly indicated disdain for the idea of hospitals giving physicians anything. It is a felony if gifts are offered or accepted with the intent of inducing unaffiliated physicians to refer patients to the hospital. The hostility and suspicion with which regulators regard gifts to physicians is now ingrained deeply into the culture of the various agencies charged with fighting “fraud and abuse.”

On the other side of the canyon, however, lawmakers have just as clearly encouraged the adoption of e-prescribing and EHR. Unfortunately, this technology costs money, which physicians have not been lining up to spend. The solution is to encourage insurers and hospitals, which also have an interest in promoting technology, to give the physicians what they need. The comments to the proposed regulations indicate internal skepticism as to whether the rules will result in more than one-in-five physicians embracing the new technology.

The OIG summed up its initiative best when it said:

> “The question as to the regulatory impact for this proposed rule is: to what extent would the use of these proposed anti-kickback safe harbors accelerate adoption of electronic prescribing and EHRs, taking into account available policy instruments, notably the development of interoperable standards? The baseline information is uncertain. As described in more detail in the physician self-referral proposed rule, there are numerous estimates of adoption of electronic prescribing by health plans, hospitals, physicians, and (for prescribing of drugs only) pharmacies. As noted there, these estimates are highly sensitive to assumptions. . . . .We are interested in comments on whether information exists that would allow more definite estimates as to the effects of these proposed safe harbors."

Unless and until the underlying policy directives are resolved, the regulatory ambivalence towards promoting technology will remain. Both the OIG and CMS regard prohibiting hospitals and insurers from giving physicians anything of value as one of their reasons for being. This makes both agencies ill-prepared to spearhead the rapid deployment of technology to physicians at the expense of hospitals and insurers. As a result, the need for thoughtful and informative comments from industry prior to the adoption of final regulations is particularly important. Without the benefit of a new perspective on the part of the agencies, gifts of technology to physicians from hospitals and insurers may continue to contain an element of peril for some time to come.

For more information, please contact:

Author:
Thomas E. Jeffry, Jr.
Los Angeles, California
(213) 633-6882
TomJeffry@dwt.com

Other DWT Contacts:
Edwin D. Rauzi, Seattle, (206) 628-7761, EdRauzi@dwt.com
Paul T. Smith, San Francisco, (415) 276-6532, PaulSmith@dwt.com

return to Advisory Bulletins main page